

REMARKS

Claims 1 - 15 are pending in the instant matter. Claims 1 - 15 stand rejected. Claims 10 and 15 have been cancelled, claims 1, 6, 7, 8 and 13 have been amended, and are each believed to recite allowable subject matter. Notice to that effect is hereby earnestly solicited. Attempts to do this with the Examiner by way of telephone conference are ongoing.

The Examiner's availability to discuss the instant matter, and helpful and productive comments are appreciated. To those ends, applicants' undersigned representative invites any constructive dialogue at 949.732.6507 if any progress is possible, as this matter was granted "Special" status on the basis of actual manufacture, and assignee awaits the issuance of the instant matter, as discussed in said Petition to protect its significant investment in this technology and current market launch.

DRAWINGS

Applicants submit herewith a revised version of Fig. 3, styled --REPLACEMENT SHEET--, wherein reference designator number (501) [sic] has been replaced with "(581)", per the Examiner's helpful suggestion.

Claim Rejections - 35 U.S.C. Section 112

Applicants have cancelled claims 10 and 15, and invite suggestions from the Examiner to eliminate any ambiguity real or perceived moving forward, this action believed to have mooted the rejections.

Claim Rejections - 35 U.S.C. Section 102

Claims 1 - 7, 9, 11 and 13 stand rejected as anticipated by Dardik's United States Letters Patent Number 4,250,887. Claim 1 has been amended to read:

Claim 1 (Amended) A pumping system having built-in safety features including an air purge mechanism within a syringe connector, comprising, in combination:

a source of fluid for selective pressurization,
a mechanism for applying pressure to said fluid,
a conduit for selectively carrying said fluid from said
source when said fluid is pressurized and
a container, of a viscous material connected to said
conduit to receive pressurized fluid from said conduit to selectively force
said viscous material from said container, whereby the system is effective
for pumping at moderate to high pressures during surgical procedures
without risk to patients.

The Dardick reference does not recite having built-in safety features; having an air purge mechanism within a syringe connector; or whereby the system is effective for pumping at moderate to high pressures during surgical procedures without risk to patients each of which is included in the present invention. Since these features are not literally present within the Dardick reference, reconsideration of the rejection of claim 1 and its dependents is respectfully requested. Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715 (Fed. Cir. 1984).

Claim 13 now recites:

Claim 13 (Amended): A pumping system for medical device usage having a hydraulic connection comprising, in combination:

a source of fluid for selective pressurization,
handle means for supporting said source of fluid
a mechanism for applying pressure to said fluid, said
mechanism comprises,

**trigger means mounted to said handle means for selectively applying pressure to said fluid in said source of fluid,
a conduit for selectively carrying said fluid from said source when said fluid is pressurized, and
a container of a viscous material connected to said conduit to receive pressurized fluid from said conduit to selectively force said viscous material from said container;
whereby automatic purging of air provides an effective incompressible working fluid preventing over pressurization within the self-contained fluid reservoir.**

The Dardick reference does not recite having a hydraulic connection; whereby automatic purging of air provides an effective incompressible working fluid preventing over pressurization within the self-contained fluid reservoir each of which is included in the present invention. Since these features are not literally present within the Dardick reference, reconsideration of the rejection of claim 13 is respectfully requested.

Likewise, the anticipation rejection cannot be sustained over Dardick because, as admitted by the Examiner at Page 4, line 4 of the instant Office Action: the Dardick reference lacks "valves mounted in the housing for controlling the movement of fluid and a manual pressure release mechanism."

In sum , for these reasons, and those stated above, the anticipation rejections cannot be sustained. Reversal is therefore respectfully requested under both the facts of this case, and the law, as "each and every component of a patent claim must be shown in a single reference" to uphold an anticipation rejection. Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715 (Fed. Cir. 1984). Such relief is hereby earnestly solicited.

Claim Rejections - 35 U.S.C. Section 103

The Examiner rejects claims 8, 12, and 14 as obvious over the Dardick reference in view of United States Letters Patent No. 5,015,233 issued to McGough. Reconsideration and reversal of these rejections is hereby earnestly solicited. The KSR case has compelled new levels of scrutiny in this area, but it respectfully proposed that *a combination that introduces something new and produces at least one of a new function and an unexpected result remains non-obvious, and therefore patentable.* KSR International v. Teleflex, 82 USPQ 2d 1383 (U.S. 2007).

The Examiner begins this rejection set by reciting that the Dardick reference lacks valves mounted in the housing for controlling the movement of fluid and a manual pressure release mechanism. This true statement is important to consider, when one considers the functions of the references and the present invention, respectively.

Dardick is for injecting a (non-viscous) radiopaque dye into a patient's artery. MCGough is for inflating balloons, for example, for angioplasty. It is respectfully submitted that *neither of these devices are designed to, or can work at moderate to high pressures.* For this reason, neither of them have built-in safety features.

In contradistinction, the present invention is designed to, and does push viscous material (cement) into the spine with the use of a secondary incompressible fluid. See, for example, the specification at page three, first two full paragraphs. Owing to this unique system approach, an air purge is designed into the syringe connector. The removable connection to the syringe allows the syringe to be filled.

This *new function, namely the hydraulic connection does not exist in either Dardick or McGough.* The *unexpected benefit* of incorporating a feature to automatically purge air from the system arises from the use of an effectively incompressible working fluid. This results in a safety mechanism (explained below) and

is affirmatively claimed as recited in both independent claims 1 (from which 8 and 12 each depends) and 13 (from which 14 depends):

Claim 1 (Amended) A pumping system having built-in safety features and having an air purge mechanism within a syringe connector, comprising, in combination:

a source of fluid for selective pressurization,
a mechanism for applying pressure to said fluid,
a conduit for selectively carrying said fluid from said source when said fluid is pressurized and
a container, of a viscous material connected to said conduit to receive pressurized fluid from said conduit to selectively force said viscous material from said container, whereby the system is effective for pumping at moderate to high pressures during surgical procedures without risk to patients.

Claim 13 (Amended): A pumping system for medical device usage having a hydraulic connection comprising

a source of fluid for selective pressurization,
handle means for supporting said source of fluid
a mechanism for applying pressure to said fluid, said mechanism comprises,
trigger means mounted to said handle means for selectively applying pressure to said fluid in said source of fluid,
a conduit for selectively carrying said fluid from said source when said fluid is pressurized, and
a container of a viscous material connected to said conduit to receive pressurized fluid from said conduit to selectively force said viscous material from said container;

whereby automatic purging of air provides an effective incompressible working fluid preventing over pressurization within the self-contained fluid reservoir acting as a fail-safe safety mechanism.

Just to reiterate - Dardick describes fluid purged of air but teaches no means to do so, and McGough and Dardick both use intermediate plungers to push on a standard syringe. Likewise, where Dardick described adjusting ratios of the drive syringe to the driven syringe to compensate for the "loss of feel" caused by the intermediate syringes. There is no force amplification by repetitive pumping action.

None of the devices have a self contained fluid reservoir, which the present invention does and the safety feature inherent therein is the prevention of overpressurization. According to the teachings of the present invention, a self-contained fluid reservoir and the related features allow for the high pressure, safe pumping of viscous material into a patient's spine by a doctor.

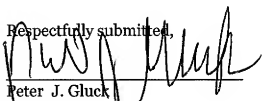
It is respectfully submitted that this is the prototypical case of *a combination that introduces something new (a self-contained fluid reservoir) and produces at least one of a new function (safety feature of no overpressurization, with the air purge in the syringe connector) and an unexpected result (the ability to push cement at high pressure without overpressurization) and it thus remains non-obvious, and therefore patentable.* KSR International v. Teleflex, 82 USPQ 2d 1383 (U.S. 2007).

Such relief is hereby earnestly solicited, and any fees required may be debited from deposit account number 50,2638.

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[MARKED-UP VERSION OF] AMENDMENTS TO THE CLAIMS

Claim 1 (Amended) A pumping system having built-in safety features comprising, in combination:

- a source of fluid for selective pressurization,
- a mechanism for applying pressure to said fluid,
- a conduit for selectively carrying said fluid from said source when

said fluid is pressurized and

a container, having an air purge mechanism within a syringe connector, of a viscous material connected to said conduit to receive pressurized fluid from said conduit to selectively force said viscous material from said container, whereby the system is effective for pumping at moderate to high pressures during surgical procedures without risk to patients.

Claim 2 (Original): The system recited in claim 1 wherein said conduit is a flexible tube.

Claim 3 (Original): The system recited in claim 1 wherein said source of fluid comprises a reservoir for storing said fluid.

Claim 4 (Original): The system recited in claim 1 wherein said fluid is an incompressible liquid.

Claim 5 (Cancelled): ~~The system recited in claim 1 wherein said container comprises a syringe.~~

Claim 6 (Amended): The system recited in claim 1 including a handle device means for supporting said source of fluid.

Claim 7 (Amended): The system recited in claim 6 wherein said mechanism for applying pressure to said fluid comprises,

trigger means mounted to said handle device means for selectively applying pressure to said fluid in said source of fluid.

Claim 8 (Amended): The system recited in claim 6 including,
housing means formed with said handle device means , and
valve means mounted in said housing means for controlling the
movement of said fluid from said source of fluid through said conduit.

Claim 9 (Original): The system recited in claim 1 including connector means for connecting said conduit to said container.

Claim 10 (Cancelled): ~~The system recited in claim 9 wherein said connector means rotates about said conduit to permit selective bleeding of air from said container.~~

Claim 11 (Original): The system recited in claim 5 wherein said syringe includes a plunger movable therein.

Claim 12 (Original): The system recited in claim 1 including, a manual pressure release mechanism operatively connected to said source of fluid for selectively relieving pressure from said fluid.

Claim 13 (Amended): A pumping system for medical device usage having a hydraulic connection comprising

a source of fluid for selective pressurization,
handle means for supporting said source of fluid
a mechanism for applying pressure to said fluid, said mechanism
comprises,
trigger means mounted to said handle means for selectively applying
pressure to said fluid in said source of fluid,
a conduit for selectively carrying said fluid from said source when said
fluid is pressurized, and

a container of a viscous material connected to said conduit to receive pressurized fluid from said conduit to selectively force said viscous material from said container;

whereby automatic purging of air provides an effective incompressible working fluid preventing over pressurization within the self-contained fluid reservoir acting as a fail-safe safety mechanism.

Claim 14 (original): The system recited in claim 13 including housing means formed with said handle means valve means mounted in said housing means for controlling the movement of said fluid from said source of fluid through said conduit, and connector means for connecting said conduit to said container.

Claim 15 (Cancelled).